REMARKS

The Examiner issued a Restriction Requirement indicating that claims 1-23 of Group I and claims 24-30 of Group II were directed to two patently distinct species of the claimed invention. (*11/18/05 Office Action*, p. 2). During a phone interview on June 7, 2005, the Applicants provisionally elected without traverse to prosecute claims 1-23 of Group I. Claims 9 and 24-30 have been canceled without prejudice. Therefore, claims 1- 8 and 10 - 23 are now pending in this application. Claims 1, 5, 11, 12 and 22 have been amended to particularly point out and distinctly claim the subject matter of the invention. No new matter has been added. In view of the above amendments and the following remarks, it is respectfully submitted that all of the above-identified claims are allowable.

I. Claim Objections

The Examiner has objected to claim 11 stating that "claim 11 refers back to itself." (*11/18/05 Office Action*, p. 3). Claim 11 has been amended to depend from claim 1. Accordingly, it is respectfully requested that this objection be withdrawn.

II. Information Disclosure Statement

The Examiner stated that "the references cited in the Search Report: General Surgical Innovations, http://www.americanwebsite.com/comps1/gsi/pages/corporate/profile.htm has not been considered." (*11/18/05 Office Action*, p. 3). The Applicants conducted a phone interview with the Examiner on January 18, 2006, during which the Examiner acknowledged that the file history currently includes copies of the four pages of this reference. Therefore, it is respectfully submitted that the Examiner consider the reference and provide an updated, signed PTO-Form 1449 acknowledging receipt and consideration of this reference.

III. Specification

The Examiner objected to the disclosure because "element 18 in Figure 1 is not disclosed in the specification." (*11/18/05 Office Action*, p. 4). This informality has been corrected in the above amendments to paragraphs [0012], [0013], and [0027]. No new matter has been added. In view of the above amendments, it is respectfully submitted that the Examiner withdraw this objection.

IV. Claim Rejections - 35 U.S.C. § 102

Claims 1-3, 6-7, 9-17, and 19-22 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent Number 5,458,568 to Racchini et al. ("Racchini").

Claim 1 recites a "device *for preventing closure of a surgically created resection cavity*" comprising "an insertion member having . . ."an outer diameter of approximately 5 FR to 10 FR" and "an inflatable member deployable from the distal end of the insertion member, an inner chamber of the inflatable member being fluidly coupled to the lumen to receive an inflation fluid therefrom so that, when the inflation fluid is supplied to the inflatable member, *the inflatable member expands to a substantially spherical shape* so that an outer surface of the inflatable member contacts the surrounding tissue and moves the surrounding tissue out of the resection cavity.

Claim 12 recites a surgical tissue separator comprising "*a substantially spherical expandable portion* insertable in a surgically created body cavity in combination with a catheter portion adapted to position the expandable portion in the cavity, the expandable portion being deployable from the catheter portion, wherein supplying an inflation fluid to the expandable portion via a lumen of the catheter portion expands the expandable portion into contact with inner surfaces of the cavity to prevent the inner surfaces from healing together, *the catheter portion having an outer diameter of approximately 5 FR to 10 Fr.*"

In contrast, both Racchini and Segal describe catheters including substantially cylindrical balloons (or other substantially cylindrical expanding structures) for dilating vessels (e.g., Rachinni, specification, col. 1, lines 16 - 22; col. 2, lines 64 - 67; col. 4, line 64 to col. 7, line 5). Rachinni expands on this stating that "the drug delivery apparatus of the present invention has applicability for use with any body passageways including among others, blood vessels, urinary tract, intestinal tract, kidney ducts, wind pipe and the like." Similarly, Segal states that the invention is "for enlarging a flow passage of a vessel by dilating and irradiating an obstruction in the vessel." (Segal Abstract, lines1 - 3). Similarly, the Field of the Invention states that the invention relates to "percutaneous transluminal devices and methods which are used to treat obstructed (sclerotic) vessel lumina in humans." (Segal specification, col. 1, lines 16 - 18). That is, as shown in Figs. 1- 6 and 10 of Racchini and Figs. 1 - 6, 10, 13, 14 and 19 of Segal 11, the balloons of these references are cylindrical to mimic the substantially cylindrical shape of the vessels within which they will be deployed.

Furthermore, Racchini is designed to apply therapeutic compounds directly to the surfaces of the vessels so altering the shape of the balloon of this reference would frustrate the purpose of this device as it would reduce the area of contact between the balloon and the tissue to be medicated and it is respectfully submitted that Racchini neither shows nor suggests balloons of any shape other than cylindrical. Furthermore, it is respectfully submitted that Racchini not only provides no motivation for any change in shape of the balloon but that it actually teaches away from such a change. It is respectfully submitted that Segal also fails to show or suggest balloons of any shape other than cylindrical and provides no motivation for any change in the shape of the balloon.

The Examiner stated that "Racchini reasonably appears to teach and disclose every element of claims 1-3, 6-7, 9-17, and 19-22." (*11/18/05 Office Action*, p. 5). However, claim 1 of the present invention recites "a device for preventing closure of a surgically created resection cavity" that "moves the surrounding tissue out of the resection cavity." Similarly, claim 12 of the present invention recites "a surgical tissue separator" that "prevent[s] the inner surfaces [of the resection cavity] from healing together." These claim limitations are neither disclosed nor suggested in Racchini. That is, the Racchini device dilates and treats passageway walls or immediately adjacent body tissue. Specifically, Racchini focuses on "positioning a drug delivery apparatus in a body passageway" (*Racchini*, col. 3, lines 50-51) and "dilating [the] passageway and delivering a drug or combination of drugs to or through a localized area of a passageway in order to treat the localized area of the passageway or to treat a localized area of tissue located adjacent to the passageway." (*Racchini*, col. 4, line 67 to col. 5, line 4). Thus, the Racchini device is specifically positioned within body passageways and discloses treating only passageways or adjacent tissue from within a passageway. Therefore, it is respectfully submitted that Racchini neither discloses nor suggests "preventing closure of a surgically created resection cavity" or "prevent[ing] the inner surfaces [of the resection cavity] from healing together," as recited in claims 1 and 12 of the present invention and that any modifications suggested to enable the claimed use are motivated by impermissible hindsight and are not suggested by Racchini or Winkler.

Therefore, is respectfully submitted that claims 1 and 12 of the present invention are not anticipated by Racchini for at least the reasons stated above. Because claims 2-3, 6-7, 10, 11, 13-17, and 19-22 depend from, and therefore include all of the limitations of claims 1 and 12, it is respectfully submitted that these claims are also allowable for at least the reasons stated above.

V. Claim Rejections - 35 U.S.C. § 103

Claims 4-5 stand rejected under 35 U.S.C. § 103(a) as obvious over Racchini in view of U.S. Patent Number 6,059,752 to Segal. The Examiner stated that Racchini shows the invention as claimed except for "a luer at the proximal end, adapted to introduce inflation fluid to the inflatable portion via the lumen" and "a port at the proximal end." (*11/18/05 Office Action*, p. 5). To cure this deficiency, the Examiner cited Segal. However, Segal also describes a cylindrical expansion member "for enlarging a flow passage of a vessel by dilating and irradiating an obstruction in the vessel." (*Segal*, col. 2, line 67 to col. 3, line 1). It is respectfully submitted that Segal does not cure the deficiencies pointed out in regard to the anticipation rejections of the independent claim, i.e., Segal does not disclose or suggest an expandable member expanding "*to a substantially spherical shape*" as recited in claim 1 from which these claims depend. Furthermore, as described above, the substantially spherical shape of the balloon of Segal is selected to mimic the shape of the vessels in which it is to be deployed and there is no showing or suggestion that any other shape may be used for this purpose. As any other shape - especially a spherical shape - would reduce the correspondence between the shape of the balloon and that of the target vessel, it is respectfully submitted that a modification to change to such a different shape is taught away from by Segal.

It is therefore respectfully submitted that claims 4-5 are not rendered obvious by Racchini in view of Segal, and it is respectfully requested that this rejection be withdrawn.

Claim 23 stands rejected under 35 U.S.C. § 103(a) as obvious over Racchini in view of U.S. Patent Number 6,482,142 to Winkler et al. ("Winkler '142"). The Examiner stated that Racchini shows the invention as claimed except for an "expandable portion . . . sized to fill a lumpectomy resection cavity." (*11/18/05 Office Action*, p. 6). To cure this deficiency, the Examiner cited Winkler '142. However, Winkler '142 describes an apparatus with "an expandable outer surface element defining an apparatus spatial volume," a radiation source, and a means for controlling the radiation treatment. (*Winkler '142*, col. 2, lines 60-64). Although Winkler shows balloons of a variety of shapes, it is respectfully submitted that all of the balloons of Winkler are non-spherical and are specifically designed to be asymmetric with respect to an axis of the catheter. Specifically, Winkler provides means for providing asymmetric isodose curves in target tissue. (Abstract, lines 6 - 8). That is, Winkler is directed to a device for generating an "isodose profile 40 which varies radially about the longitudinal axis of the device." (Specification, col. 5, lines 14 - 15). Furthermore, as Winkler is directed to providing radiation

to tissue, the catheter of Winkler must be large enough to accommodate the radiation seeds. Thus, the diameter of the catheter of Winkler must be at least 20 FR and can not be within the claimed range of 5 - 10 FR. It is also respectfully submitted that Winkler teaches away from modifying the catheter to a size within the claimed range as this would frustrate the purpose of Winkler -- i.e., it would prevent the administration of the radiation to which Winkler is directed.

It is therefore respectfully submitted that claim 23 is not rendered obvious by Racchini in view of Winkler '142, and it is respectfully requested that this rejection be withdrawn.

Claims 8 and 18 stand rejected under 35 U.S.C. § 103(a) as obvious over Racchini in view of U.S. Patent Number 6,537,194 to Winkler ("Winkler '194"). The Examiner stated that Racchini shows the invention as claimed except for the therapeutic agent called paclitaxel. (*11/18/05 Office Action*, p. 6). To cure this deficiency, the Examiner cited Winkler '194. However, Winkler '194 also fails to show or suggest a temporary tissue spacer as claimed and provides no motivations for the modifications suggested by the Examiner which, as described above, are taught away from by Racchini, and that these claims are allowable for the same reasons stated above in regard to independent claims 1 and 12 from which all of these claims depend .

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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